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| RAWLINGS, STEPHEN L | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/099,926 | KING ET AL. | |
| | Examiner | Art Unit | |
| | Stephen L. Rawlings, Ph.D. | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Claims 1-17 are pending in the application and are currently subject to restriction.

### *Election/Restrictions*

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-1980. Claims 1, 3, 4, 8, 11, and 15, insofar as the claims are drawn to a polynucleotide comprising a polynucleotide sequence that is at least 75% identical to a polynucleotide sequence selected from the group of polynucleotide sequences consisting of SEQ ID NOs: 1-1788 and 1790-1981, the complement thereof, a fragment thereof, a degenerate variant thereof, an nucleic acid or oligonucleotide that hybridizes to said polynucleotide, an expression vector comprising said polynucleotide, a host cell comprising said vector, a composition comprising said polynucleotide, and a kit comprising said oligonucleotide, classified in class 536, subclass 23.5, class 530, subclass 24.3, class 435, subclass 320.1, and class 435, subclass 325+.

Note: If Applicant elects any one of the inventions of Groups 1-1980, Applicant must do so by specifically identifying a single polynucleotide sequence to which the claims are to be drawn during examination by identifying the corresponding sequence identification number selected from the group consisting of SEQ ID NOs: 1-1788 and 1790-1981.

Groups 1981-3960. Claims 2, 7, and 11, insofar as the claims are drawn to a polypeptide, a fusion protein comprising said polypeptide, and a composition comprising either said polypeptide or fusion protein, wherein said polypeptide comprising an amino acid sequence that is at least 70% identical to an amino acid sequence encoded by a polynucleotide

sequence selected from the group of polynucleotide sequences consisting of SEQ ID NOs: 1-1788 and 1790-1981, classified in class 530, subclass 350.

Note: If Applicant elects any one of the inventions of Groups 1981-3960, Applicant must do so by specifically identifying a single polynucleotide sequence to which the claims are to be drawn during examination by identifying the corresponding sequence identification number selected from the group consisting of SEQ ID NOs: 1-1788 and 1790-1981.

Groups 3961-5940. Claims 5, 11, and 16, insofar as the claims are drawn to an antibody or antigen-binding fragment thereof, that specifically binds a polypeptide comprising an amino acid sequence that is at least 70% identical to an amino acid sequence encoded by a polynucleotide sequence selected from the group of polynucleotide sequences consisting of SEQ ID NOs: 1-1788 and 1790-1981, a composition comprising said antibody, and a kit comprising said antibody, classified in class 530, subclass 387.9.

Note: If Applicant elects any one of the inventions of Groups 3961-5940, Applicant must do so by specifically identifying a single polynucleotide sequence to which the claims are to be drawn during examination by identifying the corresponding sequence identification number selected from the group consisting of SEQ ID NOs: 1-1788 and 1790-1981.

Groups 5941-7920. Claim 6, insofar as the claim is drawn to a method for detecting cancer in a patient comprising contacting a biological sample with a binding agent that binds a polypeptide comprising an amino acid sequence that is at least 70% identical to an amino acid sequence encoded by a polynucleotide sequence selected from the group of

polynucleotide sequences consisting of SEQ ID NOs: 1-1788 and 1790-1981, classified in class 435, subclass 7.1+.

Note: If Applicant elects any one of the inventions of Groups 5941-7920, Applicant must do so by specifically identifying a single polynucleotide sequence to which the claims are to be drawn during examination by identifying the corresponding sequence identification number selected from the group consisting of SEQ ID NOs: 1-1788 and 1790-1981.

Groups 7921-9900. Claims 9, 12, and 13, insofar as the claims are drawn to a method for stimulating and/or expanding T cells, stimulating an immune response, or treating or inhibiting the development of cancer, wherein said method comprises contacting T cells with a polypeptide comprising an amino acid sequence that is at least 70% identical to an amino acid sequence encoded by a polynucleotide sequence selected from the group of polynucleotide sequences consisting of SEQ ID NOs: 1-1788 and 1790-1981 or wherein said method comprises administering a composition comprising said polypeptide, classified in class 435, subclass 277.1.

Note: If Applicant elects any one of the inventions of Groups 7921-9900, Applicant must do so by specifically identifying a single polynucleotide sequence to which the claims are to be drawn during examination by identifying the corresponding sequence identification number selected from the group consisting of SEQ ID NOs: 1-1788 and 1790-1981.

Groups 9901-11880. Claims 9, 12, and 13, insofar as the claims are drawn to a method for stimulating and/or expanding T cells, stimulating an immune response, or treating or inhibiting the development of cancer, wherein said method comprises contacting T cells with a polynucleotide comprising a polynucleotide sequence that is at least 75% identical to a

polynucleotide sequence selected from the group of polynucleotide sequences consisting of SEQ ID NOs: 1-1788 and 1790-1981, the complement thereof, a fragment thereof, a degenerate variant thereof, or an nucleic acid that hybridizes to said polynucleotide or wherein said method comprises administering to a patient a composition comprising said polynucleotide or wherein said method comprises administering a composition comprising said polynucleotide, classified in class 514, subclass 44.

Note: If Applicant elects any one of the inventions of Groups 9901-11880, Applicant must do so by specifically identifying a single polynucleotide sequence to which the claims are to be drawn during examination by identifying the corresponding sequence identification number selected from the group consisting of SEQ ID NOs: 1-1788 and 1790-1981.

Groups 11881-13860. Claims 9, 12, and 13, insofar as the claims are drawn to a method for stimulating and/or expanding T cells, stimulating an immune response, or treating or inhibiting the development of cancer, wherein said method comprises contacting T cells with antigen-presenting cells that express a polypeptide comprising an amino acid sequence that is at least 70% identical to an amino acid sequence encoded by a polynucleotide sequence selected from the group of polynucleotide sequences consisting of SEQ ID NOs: 1-1788 and 1790-1981 or wherein said method comprises administering to a patient a composition comprising said antigen-presenting cells or wherein said method comprises administering a composition comprising said antigen-presenting cells, classified in class 435, subclass 93.21.

Note: If Applicant elects any one of the inventions of Groups 11881-13860, Applicant must do so by specifically identifying a single polynucleotide

sequence to which the claims are to be drawn during examination by identifying the corresponding sequence identification number selected from the group consisting of SEQ ID NOs: 1-1788 and 1790-1981.

Groups 13861-15840. Claims 10 and 11, insofar as the claims are drawn to a T cell population, or a composition thereof, prepared by contacting T cells with a polypeptide comprising an amino acid sequence that is at least 70% identical to an amino acid sequence encoded by a polynucleotide sequence selected from the group of polynucleotide sequences consisting of SEQ ID NOs: 1-1788 and 1790-1981, classified in class 435, subclass 372.3.

Note: If Applicant elects any one of the inventions of Groups 13861-15840, Applicant must do so by specifically identifying a single polynucleotide sequence to which the claims are to be drawn during examination by identifying the corresponding sequence identification number selected from the group consisting of SEQ ID NOs: 1-1788 and 1790-1981.

Groups 15841-17820. Claims 10 and 11, insofar as the claims are drawn to a T cell population, or a composition thereof, prepared by contacting T cells with a polynucleotide comprising a polynucleotide sequence that is at least 75% identical to a polynucleotide sequence selected from the group of polynucleotide sequences consisting of SEQ ID NOs: 1-1788 and 1790-1981, the complement thereof, a fragment thereof, a degenerate variant thereof, or an nucleic acid that hybridizes to said polynucleotide, classified in class 435, subclass 372.3.

Note: If Applicant elects any one of the inventions of Groups 15841-17820, Applicant must do so by specifically identifying a single polynucleotide sequence to which the claims are to be drawn during examination by

identifying the corresponding sequence identification number selected from the group consisting of SEQ ID NOs: 1-1788 and 1790-1981.

Groups 17821-19800. Claims 10 and 11, insofar as the claims are drawn to a T cell population, or a composition thereof, prepared by contacting T cells with by contacting T cells with antigen-presenting cells that express a polypeptide comprising an amino acid sequence that is at least 70% identical to an amino acid sequence encoded by a polynucleotide sequence selected from the group of polynucleotide sequences consisting of SEQ ID NOs: 1-1788 and 1790-1981, classified in class 435, subclass 372.3.

Note: If Applicant elects any one of the inventions of Groups 17821-19800, Applicant must do so by specifically identifying a single polynucleotide sequence to which the claims are to be drawn during examination by identifying the corresponding sequence identification number selected from the group consisting of SEQ ID NOs: 1-1788 and 1790-1981.

Groups 19801-21780. Claim 11, insofar as the claim is drawn to a composition comprising antigen-presenting cells that express a polypeptide comprising an amino acid sequence that is at least 70% identical to an amino acid sequence encoded by a polynucleotide sequence selected from the group of polynucleotide sequences consisting of SEQ ID NOs: 1-1788 and 1790-1981, classified in class 435, subclass 372.1.

Note: If Applicant elects any one of the inventions of Groups 19801-21780, Applicant must do so by specifically identifying a single polynucleotide sequence to which the claims are to be drawn during examination by

identifying the corresponding sequence identification number selected from the group consisting of SEQ ID NOs: 1-1788 and 1790-1981.

Groups 21781-23760. Claims 12 and 13, insofar as the claims are drawn to a method for stimulating an immune response, treating cancer, or inhibiting the development of cancer, wherein said method comprises administering to a patient a composition comprising antibodies that specifically binds a polypeptide comprising an amino acid sequence that is at least 70% identical to an amino acid sequence encoded by a polynucleotide sequence selected from the group of polynucleotide sequences consisting of SEQ ID NOs: 1-1788 and 1790-1981, classified, for example, in class 424, subclass 138.1.

Note: If Applicant elects any one of the inventions of Groups 21781-23760, Applicant must do so by specifically identifying a single polynucleotide sequence to which the claims are to be drawn during examination by identifying the corresponding sequence identification number selected from the group consisting of SEQ ID NOs: 1-1788 and 1790-1981.

Groups 23761-25740. Claims 12, 13, and 17, insofar as the claims are drawn to a method for stimulating an immune response, treating cancer, or inhibiting the development of cancer, wherein said method comprises administering to a patient a composition comprising T cell populations, or a composition thereof, prepared by contacting T cells with a polypeptide comprising an amino acid sequence that is at least 70% identical to an amino acid sequence encoded by a polynucleotide sequence selected from the group of polynucleotide sequences consisting of SEQ ID NOs: 1-1788 and 1790-1981, classified in class 424, subclass 93.1.

Note: If Applicant elects any one of the inventions of Groups 23761-25740, Applicant must do so by specifically identifying a single polynucleotide sequence to which the claims are to be drawn during examination by identifying the corresponding sequence identification number selected from the group consisting of SEQ ID NOs: 1-1788 and 1790-1981.

Groups 25741-27720. Claims 12, 13, and 17, insofar as the claims are drawn to a method for stimulating an immune response, treating cancer, or inhibiting the development of cancer, wherein said method comprises administering to a patient a composition comprising T cell populations, or a composition thereof, prepared by contacting T cells with a polynucleotide comprising a polynucleotide sequence that is at least 75% identical to a polynucleotide sequence selected from the group of polynucleotide sequences consisting of SEQ ID NOs: 1-1788 and 1790-1981, the complement thereof, a fragment thereof, a degenerate variant thereof, or an nucleic acid that hybridizes to said polynucleotide, classified in class 424, subclass 93.1.

Note: If Applicant elects any one of the inventions of Groups 25741-27720, Applicant must do so by specifically identifying a single polynucleotide sequence to which the claims are to be drawn during examination by identifying the corresponding sequence identification number selected from the group consisting of SEQ ID NOs: 1-1788 and 1790-1981.

Groups 27721-29700. Claims 12, 13, and 17, insofar as the claims are drawn to a method for stimulating an immune response, treating cancer, or inhibiting the development of cancer, wherein said method comprises administering to a patient a composition comprising T cell populations, or a composition thereof, prepared by contacting T cells with antigen-presenting cells that express a polypeptide comprising an amino acid

sequence that is at least 70% identical to an amino acid sequence encoded by a polynucleotide sequence selected from the group of polynucleotide sequences consisting of SEQ ID NOs: 1-1788 and 1790-198, classified in class 424, subclass 93.1.

Note: If Applicant elects any one of the inventions of Groups 27721-29700, Applicant must do so by specifically identifying a single polynucleotide sequence to which the claims are to be drawn during examination by identifying the corresponding sequence identification number selected from the group consisting of SEQ ID NOs: 1-1788 and 1790-1981.

Groups 29701-31680. Claim 14, insofar as the claim is drawn to a method for detecting cancer in a patient comprising contacting a biological sample with an oligonucleotide that hybridizes to a polynucleotide sequence selected from the group of polynucleotide sequences consisting of SEQ ID NOs: 1-1788 and 1790-1981, classified in class 435, subclass 6.

Note: If Applicant elects any one of the inventions of Groups 29701-31680, Applicant must do so by specifically identifying a single polynucleotide sequence to which the claims are to be drawn during examination by identifying the corresponding sequence identification number selected from the group consisting of SEQ ID NOs: 1-1788 and 1790-1981.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups 1-1980, the inventions of Groups 1981-3960, the inventions of Groups 3961-5940, the inventions of Groups 5941-7920, the inventions of Groups 7921-9900, the inventions of Groups 9901-11880, the inventions of Groups 11881-13860, the inventions of 13861-15840, the inventions of Groups 15841-17820, the inventions of Groups 17821-19800, the inventions of Groups 19801-21780, the

inventions of Groups 21781-23760, the inventions of Groups 23761-25740, the inventions of Groups 25741-27720, the inventions of Groups 27721-29700, and the inventions of Groups 29701-31680 are patentably distinct products, since each of the polynucleotide sequences selected from the group consisting of SEQ ID NOs: 1-1788 and 1790-1981 are different. Accordingly, the search necessary to examine claims drawn or directed to any one of the polynucleotide sequences is not the same, nor is it coextensive with the search required to examine claims drawn to any other polynucleotide sequence. Because a different search is required to examine claims drawn or directed to any one of these polynucleotides sequences, examining claims drawn or directed to more than one of these sequences would constitute a serious burden.

The inventions of Groups 1-1980, the inventions of Groups 1981-3960, the inventions of Groups 3961-5940, the inventions of Groups 13861-19800, and the inventions of Groups 19801-21780 are patentably distinct products, because the inventions of Groups 1-1980 are nucleic acid molecules, or compositions thereof, vectors, or host cells, the inventions of Groups 1981-3960 are polypeptides or compositions thereof, the inventions of Groups 3961-5940 are antibodies, antigen-binding fragments thereof, or compositions thereof, the inventions of Groups 13861-19800 are T cell populations or compositions thereof, and the inventions of Groups 19801-21780 are antigen-presenting cells or compositions thereof.

Polypeptides and polynucleotides are chemically distinct products, since polypeptides are composed of polymers of amino acids, whereas polynucleotides are composed of polymers of nucleotides. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, a polypeptide can be produced by means, other than the recombinant means by which a polynucleotide encoding a polypeptide might be used to produce the polypeptide, since a polypeptide can be produced (or isolated) by biochemical means, including, for example, affinity chromatography. In addition, while the polynucleotide might encode the polypeptide, generally, it can also

encode another polypeptide using the information provided by an alternative open reading frame; and furthermore, since a polynucleotide can be used as a probe in hybridization-based analyses, the information provided by a polynucleotide can be used isolate different polynucleotides encoding polypeptides, which have amino acid sequences that differ from the amino acid sequence encoded by the disclosed polynucleotide. Consequently, the disclosed relationship between a polynucleotide capable of encoding a polypeptide and the polypeptide is not exclusive, since either the claimed polynucleotide or the claimed polypeptide can also be related to other polynucleotides or polypeptides, which are materially and chemically different from the claimed inventions. Therefore, any one of the inventions of Groups 1-1980 and any one of the inventions of Groups 1981-3960 are patentably distinct products.

The inventions of Groups 1-1980 and the inventions of Groups 1981-3960 have acquired a separate status in the art, as evidenced by their different classifications, and the search performed in examining claims drawn to a polynucleotide is a different from the search performed in examining claims drawn to a polypeptide. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims of any one of Group 1-1980 would not suffice to provide adequate information regarding the merit of the claims of any one of Groups 1981-3960, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of any one of the inventions of Groups 1-1980 and any one of the inventions of Groups 1981-3960, an examination of more than one would constitute a serious burden. Moreover, because the disclosed relationship between the polynucleotide and the polypeptide encoded by the polynucleotide is not absolute or exclusive of other relationships with different polynucleotides or polypeptides, the search of either group will likely provide information

that is relevant to one but not the other; and as such, searching one in addition to the other would be unduly burdensome.

Since the inventions of any one of the inventions of Groups 1-1980 and any one of the inventions of Groups 1981-3960 are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of any one of Groups 1981-3960 and any one of the inventions of Groups 3961-5940 are patentably distinct because, although both are polypeptides, the inventions of Groups 1981-3960 are tumor antigens, whereas the inventions of Groups 3961-5940 are antibodies. An antibody, such as an immunoglobulin G (IgG) molecule, typically comprises four polypeptides: two light chains and two heavy chains, each containing constant and variable regions, which interact with one another to form an antigen-binding domain comprised of amino acid residues in each chain. In contrast, the cell cycle regulating protein is disclosed as consisting of a single polypeptide chain; so the inventions of Groups 1981-3960 and the inventions of Groups 3961-5940 are structurally distinct from one another. Thus, any relationship between an antibody and a polypeptide to which the antibody binds is codependent upon the structural (i.e., antigenic) information provided by the polypeptide, which is recognized as the antigenic determinant to which the antibody binds, and the selective binding nature of the antigen-binding domain of the antibody. However, a polypeptide comprises multiple antigenic determinants and can thus elicit the production of multiple different antibodies, which recognize and bind structurally distinct portions (i.e., epitopes) of the polypeptide. Furthermore, an antibody is capable of recognizing and binding antigenic determinants that are shared by polypeptides, which are otherwise structurally and/or functionally distinct from the claimed polypeptide to which it binds (e.g., a human protein's mouse homolog, or a different member of a functionally related family of proteins). Consequently, the disclosed relationship between an antibody that binds a polypeptide and the polypeptide is not exclusive, since either the claimed antibody or the claimed polypeptide can also be related to other polypeptides or antibodies, respectively, which are materially and chemically different from the claimed inventions. Therefore, the

inventions of any one of inventions of Groups 1981-3960 and any one of the inventions of Groups 3961-5940 are patentably distinct products.

Searching any one of inventions of Groups 1981-3960 and any one of the inventions of Groups 3961-5940 would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. A search of relevant sequence databases using the entire amino acid sequence of the polypeptide as query is necessary for the determination of the novelty and unobviousness of the polypeptide. However, such a search is not necessary, or sufficient to identify antibodies that bind the polypeptide, since antibodies that bind an epitope of the polypeptide may be known, even if the polypeptide is not (e.g., a anti-phosphotyrosine antibody binds a phosphotyrosine epitope, which is shared by numerous different proteins, and which would bind a novel tyrosine phosphorylated polypeptide). Accordingly, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, having to search any one of inventions of Groups 1981-3960 and any one of the inventions of Groups 3961-5940 would constitute a serious burden.

Since any one of inventions of Groups 1981-3960 and any one of the inventions of Groups 3961-5940 are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups 1-1980 and the inventions of Groups 3961-5940 are patentably distinct because a polynucleotide and an antibody are chemically distinct molecules, since a polynucleotide is composed of polymers of nucleotides, whereas antibodies are composed of polymers of amino acids. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, the claimed

polynucleotide does not encode a polypeptide chain of the claimed antibody; and the claimed antibody cannot be encoded by the claimed polynucleotide. Therefore, any one of the inventions of Groups 1-1980 and any one of the inventions of Groups 3961-5940 are patentably distinct products.

Searching any one of the inventions of Groups 1-1980 and any one of the inventions of Groups 3961-5940 would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. Therefore, having to search any one of the inventions of Groups 1-1980 and any one of the inventions of Groups 3961-5940 would constitute a serious burden.

Since any one of the inventions of Groups 1-1980 and any one of the inventions of Groups 3961-5940 are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups 13861-15840, the inventions of Groups 15841-17820, and the inventions of Groups 17821-19800 are patentably distinct because, although each is a T cell population, the inventions of Groups 13861-15840 are T cell populations prepared by contacting T cells with a polypeptide, whereas the inventions of Groups 15841-17820 are T cell populations prepared by contacting T cells with a polynucleotide and the inventions of Groups 17821-19800 are T cell populations prepared by contacting T cells with antigen-presenting cells. Accordingly, each invention is a different T cell population. For example, stimulating T cells by contact with a polypeptide is expected to produce a population of T cells that differs from a population prepared by contacting T cells with antigen-presenting cells expressing the polypeptide, because antigen-presenting cells process the polypeptide and display fragments of the polypeptide, which differ antigenically from the intact polypeptide; and similarly, stimulating T cells by contact with a polypeptide or antigen-presenting cells expressing a polypeptide is expected to produce a population of T cells that differs from a population prepared by contacting T cells with a nucleic acid molecule, since the nucleic

acid molecule is antigenically distinct from the polypeptide or fragments thereof presented by the antigen-presenting cells. Therefore, the inventions of Groups 13861-15840, the inventions of Groups 15841-17820, and the inventions of Groups 17821-19800 are patentably distinct products, which are prepared by materially different processes.

Searching more than one of any of the inventions of Groups 13861-15840, any one of the inventions of Groups 15841-17820, and any of the inventions of Groups 17821-19800 would be unduly burdensome, because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. Therefore, having to search more than one of any of the inventions of Groups 13861-15840, any one of the inventions of Groups 15841-17820, and any of the inventions of Groups 17821-19800 would constitute a serious burden.

Since any two of the inventions of Groups 13861-15840, Groups 15841-17820, and Groups 17821-19800 are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups 13861-19800 and the inventions of Groups 19801-21780 are patentably distinct because, whereas the inventions of Groups 13861-19800 are T cell populations, the inventions of Groups 19801-21780 are antigen-presenting cells. T cells and antigen-presenting cells are physiologically and morphologically distinct. Therefore, any one of the inventions of Groups 13861-19800 and any one of the inventions of Groups 19801-21780 are patentably distinct products.

Searching any one of the inventions of Groups 13861-19800 and any one of the inventions of Groups 19801-21780 would be unduly burdensome, because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. Therefore, having to search any one of the inventions of Groups 13861-19800 and any one of the inventions of Groups 19801-21780 would constitute a serious burden.

Since any one of the inventions of Groups 13861-19800 and any one of the inventions of Groups 19801-21780 are patentably distinct from the other and because

the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups 5941-7920, the inventions of Groups 7921-13860, the inventions of Groups 21781-23760, the inventions of Groups 23761-29700, and the inventions of Groups 29701-31680 are patentably distinct methods.

The inventions of Groups 5941-7920 and 29701-31680 are methods for detecting cancer in a patient, whereas the inventions of Groups 7921-13860 and 21781-29700 are methods for stimulating or expanding T cells and/or treating or inhibiting cancer. The inventions of Groups 5941-7920 and 29701-31680 and the inventions of Groups 7921-13860 and 21781-29700 are patentably distinct, since the inventions have different purposes or objectives. Furthermore, the inventions of Groups 5941-7920 and 29701-31680 and the inventions of Groups 7921-13860 and 21781-29700 are patentably distinct because the inventions are materially different methods comprising different process steps.

Searching any one of the inventions of inventions of Groups 5941-7920 and 29701-31680 and any one of the inventions of Groups 7921-13860 and 21781-29700 would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications. Moreover, the necessary searches are not the same, nor are they coextensive in nature and scope with one another, so, having to search any one of the inventions of inventions of Groups 5941-7920 and 29701-31680 and any one of the inventions of Groups 7921-13860 and 21781-29700 would constitute a serious burden.

Since any one of the inventions of inventions of Groups 5941-7920 and 29701-31680 and any one of the inventions of Groups 7921-13860 and 21781-29700 are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups 5941-7920 and the inventions of Groups 29701-31680 are patentably distinct inventions because, although both are methods for detecting cancer, the inventions of Groups 5941-7920 and the inventions of Groups 29701-31680

are materially different methods comprising different process steps, since the former inventions comprise detecting a polypeptide by contacting a biological sample with an agent that binds the polypeptide and the latter inventions comprise detecting a nucleic acid molecule by contacting a biological sample with an oligonucleotide that binds the nucleic acid molecule.

Searching any one of the inventions of Groups 5941-7920 and any one of the inventions of Groups 29701-31680 would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and because, for example, the levels of a polypeptide and the levels of a nucleic acid molecule encoding the polypeptide are not necessarily concordant. Moreover, the necessary searches are not the same, nor are they coextensive in nature and scope with one another, so, having to search any one of the inventions of Groups 5941-7920 and any one of the inventions of Groups 29701-31680 would constitute a serious burden.

Since any one of the inventions of Groups 5941-7920 and any one of the inventions of Groups 29701-31680 are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups 7921-9900, the inventions of Groups 9901-11880, the inventions of Groups 11881-13860, the inventions of Groups 21781-23760, and the inventions of Groups 23761-29700 are patentably distinct, despite having the same or similar purpose, because the inventions are materially different methods comprising different process steps. The inventions of Groups 7921-9900 comprise contacting T cells with a polypeptide or administering to a patient a composition comprising polypeptide. In contrast, the inventions of Groups 9901-11880 comprise contacting T cells with a nucleic acid molecule or administering to a patient a composition comprising a nucleic acid molecule; and the inventions of Groups 11881-13860 comprise contacting T cells with antigen-presenting cells or administering to a patient a composition comprising antigen-presenting cells. The inventions Groups 21781-23760 comprise administering to a patient an antibody; and the inventions of Groups 23761-

29700 comprise administering to a patient T cell populations or compositions thereof. For the reasons explained above, a polypeptide and the nucleic acid molecule encoding the polypeptide are patentably distinct products, and an antibody is patentably distinct from the polypeptide to which the antibody binds and from the polynucleotide encoding the polypeptide. Furthermore, as also explained above, T cell populations prepared by materially different methods comprising contacting T cells with different products are expected to differ. Accordingly, the inventions of Groups 23761-25740, the inventions of Groups 25741-27720, and the inventions of Groups 27721-29700 are patentably distinct inventions because, although each is a method comprising administering to a patient a composition comprising T cell populations, the T cell populations are different, one from the other, since they are prepared by such materially different methods.

Searching more than one of any of the inventions of Groups 7921-9900, any of the inventions of Groups 9901-11880, any of the inventions of Groups 11881-13860, any of the inventions of Groups 21781-23760, and any of the inventions of Groups 23761-29700 would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications. Searching more than one of any of the inventions of Groups 23761-25740, any of the inventions of Groups 25741-27720, and any of the inventions of Groups 27721-29700 would be unduly burdensome because, although identically classified, the inventions are divergent in nature. Moreover, in every instance, the necessary searches are not the same, nor are they coextensive in nature and scope with one another, so, having to search more than one of any of the inventions of Groups 7921-9900, any of the inventions of Groups 9901-11880, any of the inventions of Groups 11881-13860, any of the inventions of Groups 21781-23760, and any of the inventions of Groups 23761-29700 would constitute a serious burden.

Since any two of the inventions of Groups 7921-9900, the inventions of Groups 9901-11880, the inventions of Groups 11881-13860, the inventions of Groups 21781-23760, and the inventions of Groups 23761-29700 are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

Inventions in Groups 1981-3960 and inventions of Groups 7921-9900, 13861-15840, and 23761-25740 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the polypeptide or fusion protein, or a composition thereof, can be used in a materially different process of using that product, such as the process of using the polypeptide an immunogen to produce an antibody that binds to the polypeptide.

Inventions in Groups 1-1980 and inventions in Groups 9901-11880, 15841-17820, 25741-27720, and 29701-31680 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the polynucleotide, or a composition thereof, can be used in a materially different process of using that product, such as the processes of using the polynucleotide as a template to produce the polypeptide that is encoded by the polynucleotide or as a primer in polymerase chain reactions to synthesize nucleic acid molecules comprising the polynucleotide.

Inventions in Groups 3961-5940 and inventions in Groups 5941-7920 and 21781-23760 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the antibody, or a composition thereof, can be used in a materially different process of using that product, such as the process of using the antibody to capture and purify the polypeptide to which the antibody binds by affinity chromatography.

Inventions in Groups 13861-19800 and inventions in Groups 23761-29700 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the T cell population, or a composition thereof, can be used in a materially different process of using that product, such as the process of using the T cell population in an *in vitro* assay that measures cytotoxic T cell response.

Inventions in Groups 19801-21780 and invention in Groups 11881-13860 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the antigen-presenting cells, or a composition thereof, can be used in a materially different process of using that product, such as the process of using the antigen-presenting cells in an *in vitro* assay that measures cytotoxic T cell response.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
December 6, 2004